K101135

MAY 12 2011

SLEEPWRIGHT
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510-(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

SUBMITTER INFORMATION:
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Date Summary Prepared: March 21, 2011

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Device Name: Auradorm
Device Classification Name: Anti-snoring (21CFR 872.5570)
Manufacturer: SLEEPWRIGHT
Panel: Dental
Product Code: LRK
Classification: Class II
510K # K101155/

Devices for Which Substantial Equivalence is Claimed:

Lamberg Sleep Well Device K062333
Snore Guard K103004
Acrylic Herbst Appliance K083209

Device Description:

The Auradorm Sleep Appliance is a one piece oral appliance used for reducing snoring and the effects of mild to moderate obstructive sleep apnea. The one piece upper and lower tooth engaging appliance covers the occlusal and buccal aspects of the entire lower arch teeth and the occlusal and buccal aspects of the posterior maxillary teeth to include the

maxillary canines. The maxillary central and lateral incisors do not touch the appliance. The device does not rest or impinge on soft tissue. The oral appliance is prescribed by a dentist and custom fit to the patient's mouth in the dental clinic. The oral appliance is made of FDA approved dental acrylic or resin, stainless steel ball clasps and orthodontic stainless steel braid embedded in the acrylic for strengthening purposes. The appliance is designed to limit the amount of material on the lingual aspect of the teeth and still maintain the anti-snoring functionality based on the predicate devices. The appliance has an anterior opening to prevent restriction of mouth breathing and is reinforced with orthodontic stainless steel metal braid embedded in the acrylic. Ball clasps are situated in the appliance to provide upper and lower tooth retention and adjustability for patient comfort.

The prescribing dentist determines the exact repositioning of the lower jaw via a bite registration obtained from the patient in the clinic. The dentist is able to fine tune the jaw position clinically by trying different bite registrations. The final bite registration is held in the patient's mouth to discern jaw comfort and ability to breath comfortably.

The functional relationship built into the appliance positions the mandible forward and open more vertically from it's normal location which causes a protrusion of the mandible in relation to the maxilla. This forward repositioning, which is temporary while the appliance is being used increases pharyngeal space which assists the patient with improved air exchange.

Intended Use of the Device:

The Auradorm Sleep Appliance is a dentist prescribed mandibular repositioning device worn during sleep to reduce the incidence of snoring and reduce the effects of mild to moderate obstructive sleep apnea for patients 18 years or older.

Comparison to Predicate Device:

DEVICE:	AURADORM	Lamberg Sleep Well Device K062333	Snore Guard K103004	Acrylic Splint Herbst K083209
Attribute:				
Overnight use	Yes	Yes	Yes	Yes
Single patient multi-use	Yes	Yes	Yes	Yes
Easily removed from the mouth	Yes	Yes	Yes	Yes
Can be adjusted or refit	Yes	Yes	Yes	Yes
Cleaned and inspected daily	Yes	Yes	Yes	Yes
Placed in mouth each night	Yes	Yes	Yes	Yes
Use at home or sleep lab	Yes	Yes	Yes	Yes
Prevents grinding of teeth	Yes	Yes	Yes	Yes
Dentist prescribed device	Yes	Yes	Yes	Yes
FEATURES:				
ACTION:				
Mandibular repositioning	Yes	Yes	Yes	Yes
DESIGN:				
Custom fit for each patient	Yes	Yes	Yes	Yes
Acrylic fits over upper and lower teeth	Yes	Yes	Yes	Yes

Materials:				
Non-sterile Dental Acrylic (Methyl methacrylate)	Yes	Yes	Yes	Yes
Dental Resin	Yes	No	No	Yes
Metal Ball Clasps (Stainless Steel)	Yes	Yes	No	Yes
Orthodontic metal braid (Stainless Steel)	Yes	No	No	No

Technological Characteristics Summary of Auradorm:

1. An acrylic or resin based oral appliance
2. Jaw Repositioning
3. Single patient custom fit
4. Dentist prescribed intra-oral device
5. Environment - home/sleep laboratory
6. Removable
7. Non- Sterile
8. Intended to reduce snoring and mild to moderate obstructive sleep apnea
9. Custom fit to mandibular teeth and engages the maxillary teeth

Safety and Efficacy:

The Auradorm Sleep Appliance is based on the principles of repositioning the mandible to open the airway which is similar to many marketed anti-snoring devices. This appliance is made of FDA approved dental acrylic, ball clasps and embedded orthodontic stainless steel braid.

Risks to Health: Oral appliances can cause gingival soreness, movement of teeth, periodontal issues, temporomandibular joint or muscle pain, may obstruct the airway or change results of a polysomnogram. The auradorm sleep appliance has addressed these risks through specific design features as noted below:

Soft tissue soreness: The appliance is custom fit to the patient's natural dentition and does not rest on or touch gingival tissue.

TMD Concerns: The Auradorm accomplishes the goal of increasing the airway by repositioning the lower jaw down and forward. It is recognized by the dental community that this altered jaw relationship can also affect the temporomandibular joints. The prescribing dentist should perform a TMJ examination prior to using the Auradorm to make sure the patientis not predisposed to TMD risks that may be aggravated by using the appliance. Some patients do report sensations in the TMJ area in the early stages of appliance wear, but these are usually transitory with continued use. The prescribing dentist can also slightly alter the jaw position by adjusting the acrylic of the appliance. If discomfort persists a new bite registration can be taken to fabricate a new appliance. Should TMJ pain persist, the patient can decide with their dentist to stop discontinue treatment with this modality.

Obstruction of Oral Breathing: The Auradorm will not obstruct oral breathing due to the anterior opening created in the design of the appliance. The Auradorm also increases the airway by limiting the amount of acrylic on the lingual aspect of the teeth. This allows more tongue space in the anterior part of the oral cavity and increases the pharyngeal space which is the goal of all anterior repositioning devices. It is commonly accepted in the dental community that anterior positioning of the tongue and mandible increases pharyngeal space

that improves air exchange.

Loosening or flaring of teeth: The auradorm is fabricated to minimize tooth movement due to occlusal coverage of all teeth except the maxillary central and lateral incisors. The full posterior occlusal coverage of teeth reduces local forces and pressure on inidvidual teeth or segments of teeth like lower anteriors . The dentist is also able to easily control pressure on teeth by adjusting the acrylic which can reduce the forces directed to individual teeth and supporting alveolar structures.

Polysomnogram Results: Before a dentist prescribes an Auradorm, the patient must receive a complete dental examination, a complete TMJ evaluation, and a complete medical examination which includes a sleep study by a certified sleep physician. The prescribing dentist should consider the medical history of the patients, including history of asthma, breathing or respiratory disorders, or other relevant health problems and should refer the patient to the appropriate health care provider before prescribing the device. Follow-up sleep studies with the patient using the device is highly recommended to ensure that the desired effects are achieved.

Material Composition: The Auradorm is fabricated from known dental materials used for decades throughout the industry.

The Auradorm contains or uses the following materials:
Stainless Steel (304 or 316) - Stainless steel is a commonly accepted material for dental products. All Auradorm metal components are manufactured with 304 or 316 Stainless Steel.
Dental Acrylic - The Auradorm is typically made with a methyl methacrylate formulation for the acrylic portions of the appliance. Methyl methacrylate has been used in the dental industry for well over 50 years and does not pose any known health hazards to the patient in its polymerized form. The dentist may also request the appliance to be fabricated with FDA approved dental resin.

Intended Use Statement: The Auradorm is a dentist prescribed sleep appliance which is worn during sleep by individuals 18 years or older, who want to reduce the incidence of snoring or mild to moderate obstructive sleep apnea.

Summary Report: The Auradorm is substantially equivalent to the predicates because the device is a one piece maxillary and mandibular teeth engaging oral appliance made of FDA approved dental acrylic or resin, and commonly used orthodontic materials. This device has the same intended uses as the Snore Guard, Lamberg Sleep Well Device, and Acrylic Splint Herbst appliance, and is constructed with the same materials currently used by dentists to make anti-bruxing or night guards. The minor differences in the Auradorm's technological characteristics do not raise any new questions of safety or effectiveness, thus the Auradorm is substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Cynthia Wright
Auradorm
Sleepwright
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MAY 1 2 2011

Re: K101155
Trade/Device Name: Auradorm (Neuromuscular Sleep)
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Device for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: March 21, 2011
Received: March 31, 2011

Dear Ms. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

Revision Date: February 27, 2011

SUBMITTER INFORMATION:
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Indications for Use

Common Name: Anti-snoring appliance
Device Classification Name: Anti-snoring (21CFR 872.5570)
Manufacturer: SLEEPWRIGHT
Panel: Dental
Product Code: LRK
Classification: Class II
510K # K101155

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Prescription Use _YES_____ AND/OR Over-The-Counter Use __NO_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101155